REMARKS

The Examiner provides two new references in combination with one old reference in the context of a number of new rejections which are rebutted in the following order:

I. Claims 27-29, 31, 33-41, 43 and 44 are rejected under 35 U.S.C. § 112, ¶ 2 as allegedly being indefinite.

II. Claims 27, 31, 33, 34, 36, 37, 40, 41, and 44 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by United States Patent Number 6,654,639 To Lu..

III. Rejections Under 35 USC § 103(a)

A. Claims 27-29, 31, 33-34, 36-41 and 44 are rejected under as allegedly unpatentable over United States Patent Number 6,813518 To Kupper in view of United States Patent Number 6,654,639 To Lu, further in view of United States Patent Number 6,243,603 To Ideker et al..

B. Claims 28, 29, 38, and 39 are rejected under 35 USC § 103(a) as allegedly unpatentable over United States Patent Number 6,654,639 To Lu in view of United States Patent Number 6,813518 To Kupper.

C. Claims 35 and 43 are rejected under 35 USC § 103(a) as allegedly being unpatentable under United States Patent Number 6,654,639 To Lu.

D. Claims 35 and 43 are rejected under 35 USC § 103(a) as allegedly being unpatentable under United States Patent Number 6,813518 To Kupper in view of United States Patent Number 6,654,639 To Lu, further in view of United States Patent Number 6,243,603 To Ideker et al.

I. Claims 27-29, 31, 33-41, 43 and 44 Are Not Indefinite

The Examiner states that:

> In claim 27 (and similarly claim 37), line 5, "wherein said device is configured ..." is vague since the device comprises three elements, a), b), and c), and it is unclear what element is actually configured to determine an earliest arriving signal. In line 6, "detected by said ... electrodes" is vague since the electrodes have not been set forth to detect electrical signals.

Office Action pg 2, and

> Claims 27 and 37 only contain a timing device to identify the origin of arrhythmia and do not contain an element to deliver the simultaneous pulses or provide a nexus/relationship between the delivery of the simultaneous pulses, detection of the earlier arriving pulse and identification of origin.

Office Action pg 5. The Applicants disagree and submit that the Applicant has described the relationships of all these elements in the pending claims such that one having ordinary skill in the art would understand the claim based upon the reading of the entire specification.

Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have redafted Claims 27 and 37 to clarify the relationships between the claimed elements. The redrafting of Claims 27 and 37 has clarified the preamble such that the "device" is an "implanted cardiac defibrillator device"[1] wherein the device comprises "a pacemaker":

> One example illustrated herein, describes a system that detects an earliest arriving electrical signal comprising integrated single device such as an implantable cardiac defibrillator comprising a pacemaker.

[1] Previously recieted in pending step (b).

Applicants' Specification pg 10 ln 14-16 [emphasis added]. Also, the previously recited claim element "simultaneous anti-tachycardia pacing bursts" has been reintroduced in association with the pacemaker element:

> The standard burst generator pacemaker employs appropriate technology for the generation of stimulation pulses in the form of individual pulses or pulse trains ...

Applicant's Specification pg 14 ln 16-17 [emphasis added]. The previously recited element "blanking period" has also been reintroduced in association with the pacemaker's anti-tachycardia pacing bursts:

> Specifically, a blanking period is the shortest period of time, in milliseconds, as measured from the last ATP pacing burst that would include the first captured electrogram (EGM) activity from either the atrial and ventricular channels that varies as function oftachycardial cycle length.

Applicant's Specification pg 9 ln 6-8 [emphasis added].

The Applicant's submit that the Examiner's assertion that the element detecting the earliest arriving signal is vague has not taken into account the following:

> ... the ICD then determines whether the atrial channel or the ventricular channel recorded the first electrical activity after a blanking period (i.e., for example, for a length of, but not limited to, 200 msec) following the anti-tachycardia pacing burst.

Applicant's Specification pg 19 ln 12-15 [emphasis added]; *See, The Second Saba Declaration ¶ 4*. Consequently, the pending claims properly recite that "the device" determines the earliest arriving electrical signal. However, due to the above amendment to the preamble, this recitation is further clarified as "said implanted cardiac defibrillator device".

Further, a clarified antecedent basis has been provided in the introduction of the atrial and ventricular leads to recite that these leads detect an earliest arriving electrical signal. These amendments are made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application.

The Examiner is respectfully requested to withdraw the present rejection.

I. Claims 27, 31, 33, 34, 36, 37, 40, 41, and 44 Are Not Anticipated By Lu.

The Examiner states that:

> Note Lu's system and method is capable of meeting the functional use recitations presented in the claims of delivering simulatneous pacing bursts from the electrodes and detecting the earliest signal since Lu's electrodes are capable of delivering pacing pulses and do detect the earliest signals and that he claims have not set forth any element to actually generate and deliver simultaneous pulses.

Office Action pg 3. The Applicants disagree and submit that the above claim amendments now clarify the significant differences between Lu and the Applicant's claimed embodiment. Lu does not deliver simultaneous pacing bursts to each heart chamber but are provided "with a delay" between the different heart chambers:

> Embodiments of the present invention use an intrinsic chamber activation sequence and associated interchamber time delays, preferably automatically detected during a period of time when a pathologic tachycardia is not present, to treat a pathologic tachycardia should it occur ...

Lu, col 2 ln 5-10, and

> If the originating chamber is not the right atrium, pacing will be applied according to the predetermined sequence and interchamber delays synchronized to the signal in the originating chamber. The scaled pacing template is initially synchronized (subject to a delay corresponding to the I_{ATP}, value) to the intrinsic signal from the tachycardia originating chamber.

Lu, col 11 ln 66 - col 12 ln 5. The Applicants further point out that Lu does not even use the term "simultaneous" or a closely similar phrase such as "at the same time". Clearly, Lu identifies the cardiac origin of the arrythmia before an anti-tachycardia burst is generated, and then tailors the pulse to the cardiac origin of the arrythmia.

Because Lu is delivering an anti-tachycardia pulse to a single arrythmic region, the device is incapable of creating a blanking period. Consequently, Lu's device cannot monitor for any earliest arriving electrical signal after delivery an ATP to a single cardiac chamber. Further, Lu only describes terminating arrythmia's, as opposed to diagnosing different kinds of arrythmia's after a single chamber ATP burst:

> In the case where the stimulation device 10 is intended to operate as an implantable cardioverter/defibrillator (ICD) device, it must detect the occurrence of an arrhythmia and automatically apply an appropriate electrical shock therapy to the heart aimed at terminating the detected arrhythmia.

Lu col 8 ln 62-66 [emphasis added}. Because Lu does not contemplate a device for diagnosing between different types of arrythmia, nor provides dual chamber simultaneous ATP bursts, Lu does not anticipate the presently claimed embodiment.

The Examiner is respectfully requested to withdraw the present rejection.

II. The Claims Are Not Obvious

Obviousness is determined based upon an evaluation of differences between the claimed embodiment and the asserted prior art:

> In *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 86 S. Ct. 684, 15 L. Ed. 2d 545 (1966), the Court set out a framework for applying the statutory language of § 103 ... "Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained ...

KSR v. Teleflex, 127 S. Ct. 1727, 1734 (2007). The Supreme Court in *KSR* identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in Graham:

> The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.

MPEP § 2143. The Examiner's present obviousness rejection is clearly based upon the rationale of 'predictablity' of combining old elements. The present standards to show predicatiblity are as follows:

> To reject a claim based on this rationale, Office personnel must resolve the Graham factual inquiries. Then, Office personnel must articulate the following:

(1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference ...

(2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely performs the same function as it does separately;

(3) a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable ...

MPEP §2143 Examples of Basic Requirements of a Prima Facie Case of Obviousness [emphasis added]. In other words, in order find a prima facie case of obviousness, the Examiner must prevail on all three findings. Consequently, a failure on any one prevents the formation of a *prima facie* case of obviousness.

In each of the Examiner's proposed combination of references, there is no "finding that the prior art included each element claimed". Consquently, the Examienr has failed to meet the above Requirement (1). It should be noted that Requirement (2) and Requirement (3) are premised upon a finding of all the elements under Requirement (1). Consequently, because Requirement (1), has not been met, Requirement (2) and Requirement (3) have not been met either. Consequently, as rebutted below, the Examiner has failed to create a *prima facie* case of obviousness with any of the asserted reference combinations.

A. Claims 27-29, 31, 33-34, 36-41 and 44 Are Not Obvious Under Kupper, Lu and Ideker.

The Examiner states that:

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the therapy system and method as taught by Kupper, the timing device to identify that said origin of an arrhythmia from the earliest arriving electrical signal is a SVT, VT or AV nodal tachy as taught by Lu or Ideker since such modification would provide the predictable results of

> delivering appropriate therapy based on the origin and to the appropriate heart chamber.

Office Action pg 4. The Applicants disagree because the Examiner has not shown that the combination of Kupper, Lu, or Ideker teach a device configured to provide simultaneous anti-tachycardia pacing bursts that generate a blanking period, such that an arrythmia may be diagnosed by determining an earliest arriving signal subsequent to the blanking period.

Kupper's device delivers simultaneous atrial and ventricular pacing bursts that induces a ventricular systole with the purpose of terminating the arrythmia, not generating a blanking period for the purpose of diagnosing the arrythmia. Specifically, the Examiner has overlooked the technical differences between Kupper and the Applicant's claimed embodiment when citing the following:

> Thus, a need exists in the medical arts for use of combipolar pacing of cardiac tissue to induce a ventricular extrasystole in order to simultaneously terminate atrial fibrillation of the cardiac tissue.

Kupper, col 2 ln 16-19 [emphasis added], and

> For example, several combipolar pacing pulses may be delivered before a ventricular extra-systole and termination of atrial fibrillation is achieved.

Kupper, col 11 ln 53-55 [emphasis added], and

> Simultaneous, combipolar pacing of the area of cardiac tissue may be stopped once the ventricular extra-systole has been delivered and redetection of the atrial rhythm shows a regular function.

Kupper, col 3 ln 64-67 [emphasis added]. In contrast, the Applicant's claims recite that pacing induces a "blanking period" that is characterized by an electrical quiescent period:

> As used herein, the term "blanking period" refers to any cessation of electrogram (EGM) activity from either an atrial or ventricular chamber.

Applicant's Specification, pg 9 ln 3-4. Clearly, the Applicant's "blanking period" induced by the simultaneous ATP burst eliminates all cardiac activity. Consequently, Kupper's induction of a ventricular extra-systole requires electrical activity that is outside

the scope of the Applicant's claimed embodiment. Consequently, Kupper's pacing does not induce a cessation of electrogram activity during which any earliest arriving electrical signal can be detected. Kupper's pacing is contemplated to terminate the arrythmia by inducing a ventricular extra-systole before the cardiac origin and diagnosis of the arrythmia is known.

As argued above, Lu also does not contemplate a device configured to deliver simultaneous anti-tachycardia pacing bursts that generate a blanking period directed towards diagnosing cardiac arrythmia. Further, like Kupper, Lu is directed towards terminating the arrythmias using single cardiac chamber pacing, not diagnosing the arrythmias following simultaneous pacing.

Kupper and Lu are deficient as to disclosing a device for delivering simultaneous anti-tachycardia pacing bursts that generate a blanking period. Consequently, Ideker must provide this device in order to create a prima faice case of obviousness. Ideker does not contemplate such a device. Ideker describes a device with 3 leads meant to predict and/or detect the source (e.g., cardiac chamber) of origin of premature beats (e.g., PACs or PVCs) before the arrhythmia onset:

> Determination of a medical condition may be carried out by any suitable means, such as by detecting premature beats in the heart. The method of the present invention is particularly useful for identifying the chamber of premature beat origin (e.g., left ventricle, right ventricle, left atrium, or right atrium).

Ideker col. 3 ln 58-63, and

> The detector may be configured to predict cardiac arrhythmia in the patient prior to the onset of the cardiac arrhythmia, or the present occurence of cardiac arrhythmia in the patient.

Ideker col 3 ln 66 - col 4 ln 2. Clearly, Ideker teaches the detection of PACs and PVCs before an arrhythmia even exists. Further, unlike the presently claimed embodiment, Ideker does not utilize any pacing (e.g., anti-tachycardia pacing) and does not contemplate identifying the response of the actual arrhythmia to disturbance by pacing (i.e., for example, the generation of a blanking period).

In conclusion, the combination of Kupper, Lu, and Ideker does not disclose any device capable of generating anti-tachycardia pacing bursts that generate a blanking

period such that a cardiac arrhymia is diagnosed based upon determining a first arriving electrical signal subsequent to the blanking period. As such, these references do not teach all the Applicant's claimed elements such that a prima facie case of obviousness is not present.

The Applicants respectfully request that the Examiner withdraw the present rejection.

B. Claims 28, 29, 38, and 39 Are Not Obvious Under Lu And Kupper

The Examiner states that:

> It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lu, with the microprocessor configured to initiate simulataneous ATP bursts as taught by Kupper since it would provide the predictable results of a pacing system that effectively treats AF.

Office Action ¶ 31. The Applicants disagree. The Applicants disagree because based upon the above claim amendements, and arguments, Claims 27 and 37 are not obvious. Consequently, the associated dependent claims are not obvious either:

> [D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious.

In re Fritch, 972 F.2d 1260, 1266 (Fed. Cir. 1992). The Examiner is respectfully requested to withdraw the present rejection.

C. Claims 35 and 43 Are Not Obvious Over Lu

The Examiner states that:

> It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the IMD as taught by Lu ..., with the quadrapolar sensing lead since it was known in the art and the examiner is taking official notice that IMDs use quadripolar sensing leads to provide the predictable results of allowing multiple areas of the heart to be sensed with one lead by inserting a mnimal number of leads and therefore providing less trauma/problems to the heart.

Office Action ¶ 31. The Applicants disagree. The Applicants disagree because based upon the above claim amendements, and arguments, Claims 27 and 37 are not obvious. Consequently, the associated dependent claims are not obvious either:

> [D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious.

In re Fritch, 972 F.2d 1260, 1266 (Fed. Cir. 1992). The Examiner is respectfully requested to withdraw the present rejection.

D. Claims 35 and 43 Are Not Obvious Over Kupper, Lu, and Ideker

The Examiner states that:

> It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the IMD as taught by ... modifed Kupper, with the quadrapolar sensing lead since it was known in the art and the examiner is taking official notice that IMDs use quadripolar sensing leads to provide the predictable results of allowing multiple areas of the heart to be sensed with one lead by inserting a mnimal number of leads and therefore providing less trauma/problems to the heart.

Office Action ¶ 31. The Applicants disagree. The Applicants disagree because based upon the above claim amendements, and arguments, Claims 27 and 37 are not obvious. Consequently, the associated dependent claims are not obvious either:

> [D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious.

In re Fritch, 972 F.2d 1260, 1266 (Fed. Cir. 1992). The Examiner is respectfully requested to withdraw the present rejection.

CONCLUSION

Based on the arguments provided above, Applicants believe that the Claims 27-29, 31 and 33-44 are in condition for allowance. Should the Examiner believe a

telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned at 781-828-9870.

Respectfully submitted,

Dated: March 21, 2011

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